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PLEASE REPLY TO NEWARK

October 7, 2013

Via ECF

Re: Novartis Pharmaceuticals Corp., et al. v. Wockhardt USA LLC, et al.
Consolidated Civil Action No. 2:12-cv-3967 (SDW) (MCA)
Our File No. 4756.12091

The Honorable Susan D. Wigenton, U.S.D.J.
Martin Luther King Federal Building
& United States Courthouse
50 Walnut Street
Newark, New Jersey 07101

Dear Judge Wigenton:

This firm, together with the law firm of Katten Muchin Rosenman LLP, represents Defendants Strides, Inc. and Agila Specialties Private Ltd. (collectively "Strides") in the above-referenced matter.

Strides has filed two Abbreviated New Drug Applications ("ANDAs") for zoledronic acid products, ANDA Nos. 20-2650 and 20-5254. Each of these ANDAs includes a section viii statement "carve-out" to not include treatment of osteoporosis. Strides' ANDAs only seek approval of its zoledronic acid products for the treatment of Paget's disease. As such, both ANDAs present the same section viii statement "carve-out" issues relevant to the allegations of infringement. It is Strides' position that its ANDAs do not infringe the '987 patent (which claims treatment of osteoporosis) because Strides has specifically carved out that indication.

Novartis has asserted U.S. Patent No. 8,052,987 against both of Strides' ANDAs. Novartis's initial allegations of alleged infringement of the '987 patent against Strides were based on Strides' ANDA No. 20-2650.¹ In response to those allegations, Strides filed its Motion to Dismiss Count II for Failure to State a Claim ("Strides' ANDA No. 20-2650 Motion to Dismiss").² In a separate action, Novartis asserted additional claims of infringement of the '987 patent against Strides based on Strides' ANDA No. 20-5254.³ Those additional claims were consolidated into the present action.⁴ In response to the additional allegations, Strides filed its

¹ (See D.E. 1, C.A. 13-1028).

² (See D.E. 211, C.A. 13-1208).

³ (See D.E. 1, C.A. 13-5125).

⁴ (See D.E. 10, C.A. 13-5125).

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Motion to Dismiss Count II for Failure to State a Claim ("Strides' ANDA No. 20-5254 Motion to Dismiss").⁵

There have been a number of briefs filed in these actions on the issue of whether an ANDA with a section viii statement carving out treatment for osteoporosis infringes the '987 patent. We write to advise the Court of the specific briefs in the consolidated actions that Strides has or hereby joins in support of both Strides' ANDA No. 20-2650 Motion to Dismiss and Strides' ANDA No. 20-5254 Motion to Dismiss:

- Defendants Apotex Inc. and Apotex Corp.'s Motion for Judicial Notice of the FDA Response to Novartis's Citizen Petition (D.E. 177; see *also id.*, at fn. 1)
- Defendants Apotex Inc. and Apotex Corp.'s Reply Motion (D.E. 189)

If the Court would like any clarification or has any additional questions, please let us know.

Respectfully submitted,



Gregory D. Miller

cc: All counsel of record (*via ECF*)

⁵ (See D.E. 186, C.A. 12-3967).